K132266

# 510(K) Summary

SEP 30 2013

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| Submitter: | Shaser, Inc.<br>10 Maguire Road<br>Lexington, MA 02421<br>781-995-2246 |
| Contact: | Anthony Burns, Senior Director of Regulatory Affairs |
| Summary Prepared: | July 19, 2013 |
| Device Trade Name: | Shaser HRS2 RX |
| Common Name: | Light Based Hair Removal Device |
| Classification Name: | Product Code ONF: Powered Light Based Non-Laser Surgical Instrument with Thermal Effect |
| Equivalent Device: | Shaser HRS2 (K120080), Radiancy SpaTouch (K020856), Radiance SkinStation (K051671) |
| Device Description: | Shaser HRS2 RX is an IPL device with a wavelength range of 400-1200 nm. The HRS2 RX is an AC powered, portable device. Electrical requirement is 115 VAC, 15A, 50-60 Hz, single phase. |
| Intended Use: | The Shaser HRS2 RX Hair Removal System is intended to provide phototherapeutic light to the body and is generally indicated to treat dermatological conditions. It is also intended for removal of unwanted hair by using a selective photothermal treatment. The Shaser HRS2 RX Hair Removal System is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I - IV. The Shaser HRS2 RX Hair Removal System is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. |
| Comparison: | The Shaser HRS2 RX has the same intended use, the same principle of operation, similar pulse energy range, and very similar wavelength range as the SkinStation and HRS2 predicate devices. |
| Nonclinical Performance Data: | None. |
| Clinical Performance Data: | None |
| Conclusion: | The HRS2 RX is a safe and effective device for the intended use. |
| Additional Information: | None |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Shaser, Incorporated
Mr. Anthony Burns
Senior Director of Regulatory Affairs
10 Maguire Road, Suite 120
Lexington, Massachusetts 02421

September 30, 2013

Re: K132266
Trade/Device Name: Shaser HRS2 RX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: July 19, 2013
Received: July 22, 2013

Dear Mr. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K132266

Device Name: Shaser HRS2 RX

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Prescription Use ____√____ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number : K132266